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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,800	12/12/2001	Eric G. Lovett	279.353US1	9663
21186	7590	07/05/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938				
			EXAMINER	
			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,800	Applicant(s) LOVETT ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 7-14, 21-27 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 15-20 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/11/05 has been entered.

Election/Restrictions

Claims 7-14, 21-27, and 33-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/embodiments, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/10/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 15-20, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stroebel et al (5725561). Stroebel discloses the claimed invention using a cardiac electrode, 14, and sense amplifier, 24, with CPU, 32, and time interval between heart beats to activate/select the smoothing algorithm (column 9), and using different increasing and decreasing smoothing rates (column 2). In addition, Stroebel teaches the use of adjustment of at least one rate smoothing parameter in column 8, lines 36-54, column 10, lines 30-46, and column 17, and is “based” on whether the predetermined state is present since the rate smoothing is turned on when the predetermined state is present. It is noted that the claims do not say that the “adjusted parameters” include the first and second rate smoothing percentage, but only that the plurality of parameters “include” the first and second smoothing percentage. But Stroebel does not teach using percentages for the increase and decrease. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rate smoothing system and method as taught by Stroebel, with the use of percentages for the smoothing increase and decrease since it was known in the art that rate smoothing systems and methods use percentages for the increase and decrease of the smoothing to provide a smoother, less erratic, pacing rhythm.

In addition, Stroebel teaches using the time interval between heart beats, which is a “heart rate state” or a “cardiac rhythm state”. In the alternative, Stroebel discloses the claimed invention except for determining the heart rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time interval between

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beats as taught by Stroebel, with the use of heart rate since it was known in the art that the time interval between beats and heart rate are functional equivalents ($60 \times 1/\text{heart rate} = \text{time interval between beats}$) that can be used interchangeably depending on the design choice of the system and calculations being used and because the two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the time interval between beats for the heart rate.

Claims 1, 2, 15-20, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boute et al (4503857) in view of Stroebel et al (5725561).

Boute describes the use of rate smoothing (columns 9 and 10) that can be used for atrial modes (column 11, line 61), using different upward and downward rates of change (column 9, lines 49-51) and being used when the rate either increased or decreased by a certain percentage (column 9). In addition, Boute discloses adjusting the escape interval in column 9, lines 52-65. It is noted that the claims do not say that the “adjusted parameters” include the first and second rate smoothing percentage, but only that the plurality of parameters “include” the first and second smoothing percentage.

But Boute does not describe the use of a state detector to detect a predetermined state, such as a heart rate state, and to select/activate or adjust the rate smoothing based on whether the state is present. Stroebel teaches that it is known to use a state detector to detect a predetermined heart rate state or cardiac rhythm state (the time interval between two beats) to activate/select or adjust the rate smoothing based on whether the state is present to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate

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(columns 9 and 10). It is also noted that if the rate smoothing of Stroebel is activated/selected based on whether the predetermined state is present, then the rate smoothing adjustment of Boute will be “based” on whether the predetermined state is present. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rate smoothing pacer as taught by Boute, with a state detector to detect a predetermined heart rate state to activate/select or adjust the rate smoothing based on whether the state is present as taught by Stroebel, since such a modification would provide a rate smoothing pacer that uses a state detector to detect a predetermined heart rate state to activate/select or adjust the rate smoothing based on whether the state is present to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate.

In addition, Stroebel teaches using the time interval between heart beats, which is a “heart rate state” or a “cardiac rhythm state”. In the alternative, Stroebel discloses the claimed invention except for determining the heart rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time interval between beats as taught by Stroebel, with the use of heart rate since it was known in the art that the time interval between beats and heart rate are functional equivalents ($60 \times 1/\text{heart rate} = \text{time interval between beats}$) that can be used interchangeably depending on the design choice of the system and calculations being used and because the two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the time interval between beats for the heart rate.

Claims 3-6 and 29 are rejected under 35 U.S.C. 103(a) as obvious over Boute et al in view of Stroebel (or in view of Stroebel). The state detector of Boute in view of Stroebel (or Stroebel) will include some sort of comparator with a threshold input to compare the two and will include an output when the predetermined state occurs since the device operates when certain thresholds are reached (claim 3). Also, the system does select the first and second percentages based on the determined state since it will select the percentages programmed when the state is determined (claim 29).

In the alternative, Boute in view of Stroebel (or Stroebel) discloses the claimed invention except for the comparator with threshold input and state output and the selection of the first and second percentages based on the determined state. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker system and method as taught by Boute in view of Stroebel (or Stroebel), with a comparator with threshold input and state output and the selection of the first and second percentages based on the determined state since it was known in the art that pacemaker systems and methods use: a comparator with threshold input and state output to compare the heart rate to different predetermined inputs to provide an output of the comparison to allow the pacemaker to easily determine if a particular event has occurred; and the selection of the first and second percentages based on the determined state to allow multiple rates of smoothing to be used depending on the severity of the heart rate.

Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boute in view of Stroebel (or over Stroebel).

Boute in view of Stroebel (or Stroebel) discloses the claimed invention except for using a look-up table to map and select the first and second rate smoothing percentages to the predetermined state (claims 28 and 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker system and method as taught by Boute in view of Stroebel (or Stroebel), with a look-up table to map and select the first and second rate smoothing percentages to the predetermined state since it was known in the art that pacemaker systems and methods use look-up tables to map and select different values to predetermined states to save computational time and energy and to provide different values to better meet the needs of the patient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 15-20, 28-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-19 of U.S. Patent No. 6501987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the

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art at the time the invention was made to include in the patented claims the first and second smoothing percentage since it was known in the art that the smoothing percentages provide a smoother, less erratic, pacing rhythm. In addition, as evidenced by the 103 rejections above, it would have been obvious to one having ordinary skill in the art to include the further claimed limitations of claims 2-6, 15, 17-20, and 28-31 into the patented claims since it would provide a conventional rate smoothing system to effectively pace the heart.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. It is noted that the claims do not say that the "adjusted parameters" include the first and second rate smoothing percentage, but only that the plurality of parameters "include" the first and second smoothing percentage. If the applicant intends to claim that the adjusted parameters include the percentages, it is suggested to use something similar to "wherein the at least one adjusted parameter includes at least one of a first rate smoothing percentage and..."

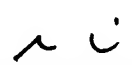
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

7/1/5

GRE
June 28, 2005